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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/249,689	05/26/94	SCHIMMEL P	MIT5261

EXAMINER
BRUSCA, J

18N2/0730

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ART UNIT	PAPER NUMBER
1805	35

DATE MAILED: 07/30/96

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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Advisory Action

Application No.	Applicant(s)
08/249,689	Schimmel
Examiner	**Group Art Unit**
John S. Brusca	1805

THE PERIOD FOR RESPONSE: [check only a) or b)]

a) ☒ expires 3 months from the mailing date of the final rejection.

b) ☐ expires either three months from the mailing date of the final rejection, or on the mailing date of this Advisory Action, whichever is later. In no event, however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

☐ Appellant's Brief is due two months from the date of the Notice of Appeal filed on _____ (or within any period for response set forth above, whichever is later). See 37 CFR 1.191(d) and 37 CFR 1.192(a).

Applicant's response to the final rejection, filed on 7/17/96 has been considered with the following effect, but is NOT deemed to place the application in condition for allowance:

☐ The proposed amendment(s):

- ☐ will be entered upon filing of a Notice of Appeal and an Appeal Brief.
- ☐ will not be entered because:
  - ☐ they raise new issues that would require further consideration and/or search. (See note below).
  - ☐ they raise the issue of new matter. (See note below).
  - ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.
  - ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: _____

☐ Applicant's response has overcome the following rejection(s):

_____

☐ Newly proposed or amended claims _____ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claims.

☒ The affidavit, exhibit or request for reconsideration has been considered but does NOT place the application in condition for allowance because:
see attachment

☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

☒ For purposes of Appeal, the status of the claims is as follows (see attached written explanation, if any):

Claims allowed: _____

Claims objected to: _____

Claims rejected: *1 and 3-21*

☐ The proposed drawing correction filed on _____ ☐ has ☐ has not been approved by the Examiner.

☐ Note the attached Information Disclosure Statement(s), PTO-1449, Paper No(s). _____ .

☐ Other

1. Applicant's arguments filed 7/22/96 have been fully considered but they are not deemed to be persuasive.

The amount of guidance or direction present is the amount of detail in the specification, as originally filed, that teaches how to make or use the invention. The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the prior art. In other words, the more that is known in the prior art about the nature of the invention and how to make and use the invention, the less that needs to be explicitly stated in the specification as originally filed. Likewise, if little is known in the prior art about the nature of the invention, to establish enablement of the invention, the specification , as originally filed, would need more detail as to how to make and use the invention. In the instant application, general teachings of drug design have been cited. However the prior art does not show the claimed method or products. Wilson et al. has been cited to show that three years after the priority date of the instant application, one of ordinary skill in the art would not know how to practice the claimed invention in the absence of additional guidance from the instant application. The Applicant has failed to point to any prior art that contests the teachings of Wilson et al., including the discussion of prior art on pages 11-12 of the Applicants response filed 7/22/96.

The Applicant states several times in their response, eg. , in the footnote on page 4, that the rejection under 35 U.S.C.§ 112, first paragraph improperly requires enablement for a therapeutic use of the product of the claimed methods and claimed products. The cited

statute requires the Applicant to teach how to make and use the claimed invention. A review of the specification reveals only one disclosed utility for the claimed invention, that being therapeutic use of the product (see pages 4 and 39-41). Because the only disclosed utility for the claimed invention is for the therapeutic use of a product of the claimed methods and therapeutic use of the claimed products, the specification must enable therapeutic use of a product of the claimed methods and therapeutic use of the claimed products. The Applicant has failed to point to any other disclosed utility. It is noted that the failure to enable/therapeutic use is only one of several reasons discussed in the Office Action mailed 8/29/95 for the rejection under 35 U.S.C. 112, first paragraph.

The Applicant states on page 6 of the response that the invention consists of a combination of established procedures. However, the Applicant has failed to cite prior art that shows synthesis of the claimed compounds. As such, the claimed invention cannot be considered to be a combination of established procedures because the invention is drawn to synthesis of compounds that are not shown in the prior art. The Applicant has failed to cite any prior art showing a therapeutic compound that interacts with the minor groove of RNA.

The Applicant objects to the statement in the Office Action mailed 8/29/95 that the guidance consists of a discussion of prior art. It was not stated or intended that discussion of prior art is improper or cannot be used to enable a claimed invention. However, the Applicant has not cited prior art that shows all steps of the claimed method or the claimed product. In particular, specific guidance is not given to make drugs that bind to the minor

groove of RNA. It is noted that all claims are drawn to a compound that binds to the minor groove of RNA, not merely to critical sites of RNA as stated on page 12 of the Applicant's response.

The Declaration filed by the Applicant 7/30/92 does not state that the claimed invention has been reduced to practice, but provides evidence of a less compelling nature consisting of the Applicant's opinion that the claimed invention could be reduced to practice by one of skill in the art. While weight has been given to the Declaration, it is not considered to provide sufficient evidence to withdraw the rejection of all claims under 35 U.S.C. § 112, first paragraph. It is noted that the Applicant has never asserted in the specification or the prosecution of the instant application that the invention has been reduced to practice.

2. Certain papers related to this application may be submitted to Art Unit 1805 by facsimile transmission. The FAX number is (703) 308-0294. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6 (d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca, Ph.D. whose telephone number is (703) 308-4231. The examiner can normally be reached on Monday through Friday from 9 AM to 5 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mindy Fleisher, Ph.D., can be reached at (703) 308-0407.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

John S. Brusca, Ph.D.

Examiner

Mindy B. F

MINDY FLEISHER
SUPERVISORY PATENT EXAMINER
GROUP 1800